

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

JANSSEN PRODUCTS, L.P. et al.,	)	
	)	
Plaintiffs,	)	Consolidated Civil Action No. 10-5954-WHW-CLW
	)	
v.	)	<b>MOTION RETURN DATE: JULY 5, 2017</b>
	)	
LUPIN LIMITED et al.,	)	<b><i>Document Electronically Filed</i></b>
	)	
Defendants.	)	
	)	

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**BRIEF IN SUPPORT OF THE PARTIES' JOINT MOTION FOR AN INDICATIVE  
RULING PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 62.1  
ON A MOTION TO MODIFY THE COURT'S FINAL JUDGMENT ORDER**

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John E. Flaherty (jflaherty@mccarter.com)  
**MCCARTER & ENGLISH LLP**  
100 Mulberry Street  
Four Gateway Center  
Newark, New Jersey 07102  
Telephone: (973) 639-7903

James E. Cecchi (JCecchi@carellabyrne.com)  
Melissa E. Flax (mflax@carellabyrne.com)  
**CARELLA, BYRNE, CECCHI, OLSTEIN,  
BRODY & AGNELLO, P.C.**  
5 Becker Farm Road  
Roseland, New Jersey 07068-1739  
Telephone: (973) 994-1700

*Of Counsel*

Gregory L. Diskant (gldiskant@pbwt.com)  
Eugene M. Gelernter  
(emgelernter@pbwt.com)  
Irena Royzman (iroyzman@pbwt.com)  
**PATTERSON BELKNAP WEBB & TYLER LLP**  
1133 Avenue of the Americas  
New York, New York 10036  
Telephone: (212) 336-2000

*Attorneys for Plaintiffs/Counterclaim-  
Defendants Janssen Products, L.P. and  
Janssen Sciences Ireland UC*

*Of Counsel*

William A. Rakoczy  
(wrakoczy@rmmslegal.com)  
Deanne M. Mazzochi  
(dmazzochi@rmmslegal.com)  
Amy D. Brody (abrody@rmmslegal.com)  
Tara M. Raghavan  
(traghavan@rmmslegal.com)  
**RAKOCZY MOLINO MAZZOCHI SIWIK LLP**  
6 West Hubbard Street, Suite 500  
Chicago, Illinois 60654  
Telephone: (312) 222-6301

*Attorneys for Defendants/Counterclaim-  
Plaintiffs Lupin Limited and Lupin  
Pharmaceuticals, Inc.*

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Pursuant to Federal Rule of Civil Procedure 62.1, Plaintiffs Janssen Products, L.P. and Janssen Sciences Ireland UC (collectively, “Plaintiffs”) and Defendants Lupin Pharmaceuticals, Inc. and Lupin Limited (collectively, “Lupin”) jointly move the Court for an “indicative ruling” on a motion under Federal Rule of Civil Procedure 60(b) to modify the injunctive provisions of the Court’s final judgment Order and trial Opinion entered on August 14, 2014 (collectively, “Final Judgment Order”) (ECF Nos. 943, 944), as they relate to Lupin in light of the recent settlement of this action.

On May 26, 2016, after full briefing of Lupin’s appeal from the Final Judgment and before oral argument in that appeal, Plaintiffs and Lupin executed a Settlement Agreement and a License Agreement (collectively, the “Agreement”) fully resolving, as relevant here, the claims and counterclaims asserted in this action relevant to Lupin and U.S. Patent Nos. 7,700,645 B2 (“the ‘645 patent”) and 7,126,015 B2 (“the ‘015 patent”) (collectively, the “Patents-in-suit”), subject to and conditioned upon modification of the Final Judgment Order as described herein. The terms of the Agreement are confidential; but as a general matter, as relevant to this action, the Agreement grants Lupin a license to market the proposed darunavir products that are the subject of Lupin Limited’s Abbreviated New Drug Application No. 202073 (“Lupin’s ANDA Products”) on a specified date before the expiration of the Patents-in-suit. The parties also agreed to approach this Court seeking a modification of certain provisions of the Final Judgment Order as they relate to Lupin. Specifically, the parties hereby request that the Court modify the final judgment Order (ECF No. 944) and the Court’s trial Opinion (ECF No. 943) underlying that Order, to allow Lupin to engage in the manufacture, use, sale, offer for sale and importation of Lupin’s ANDA Products pursuant to the terms of the Agreement. The Final Judgment Order and its underlying findings of fact and conclusions of law would otherwise remain intact.

Amending the Final Judgment Order in this manner is necessary for Lupin to exercise its license rights under the Agreement and is an express condition of the Agreement's continued effect.

This matter is currently pending on appeal in the United States Court of Appeals for the Federal Circuit (the "Federal Circuit"). Immediately following execution of the Agreement, the parties jointly sought and obtained a stay of further appellate proceedings.

Pursuant to Federal Rule of Civil Procedure 62.1, a district court, while divested of jurisdiction by a pending appeal, *see, e.g., Venen v. Sweet*, 758 F.2d 117, 120 (3d Cir. 1985), may nonetheless provide an "indicative ruling" stating that it would grant a motion under Federal Rule of Civil Procedure 60(b) if the appellate court remands for that purpose pursuant to Federal Rule of Appellate Procedure 12.1. Such an "indicative ruling" — to the effect that this Court would modify its Final Judgment Order to amend the injunctive relief provisions if the Federal Circuit should remand this case — is the precise relief the parties seek here; it is also the very type of relief for which Federal Rule of Civil Procedure 62.1 was enacted. *See* FED. R. CIV. P. 62(b), 2009 advisory committee's note. If this Court grants this Motion, the parties would then notify the Federal Circuit pursuant to Federal Rule of Appellate Procedure 12.1 and request that the Federal Circuit remand this action for entry by the Court of a modified Final Judgment Order.

### **BACKGROUND**

Plaintiffs filed the underlying consolidated litigation (Civil Action No. 10-cv-5954) against Lupin on November 15, 2010, asserting infringement of the '645 patent. On January 10, 2013, the Court granted Plaintiffs' motion for leave to file a supplemental complaint to assert infringement of, among others, the '015 patent. (ECF No. 263). Plaintiffs filed their Amended Complaint on January 18, 2013. (ECF No. 267). The Court conducted trial proceedings in this consolidated litigation between March 18, and April 9, 2014. During those trial proceedings,

Plaintiffs asserted claim 4 of the '645 patent and claim 1 of the '015 patent against Lupin. On August 14, 2014, this Court entered final judgment in favor of Plaintiffs. (ECF Nos. 943, 944).

As relevant here, Paragraphs 2, 6 and 7 of the final judgment Order provide as follows:

2) Lupin and its officers, directors, employees, agents, successors, affiliates, and assigns, and all persons and entities acting in concert or participation with them, are enjoined until the expiration of the '015 Patent from using, selling, or offering for sale in the United States, or importing into the United States, the darunavir tablets described in the Lupin ANDA, ANDA 202073, or any darunavir product that includes a bis-THF component made by any colorable variation of the process used to make Lupin's ANDA 202073 product.

6) Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Lupin's darunavir tablets in ANDA 202073 shall not be earlier than the day after the expiration of the '645 Patent and its associated pediatric exclusivity; and

7) Lupin and its officers, directors, employees, agents, successors, affiliates, and assigns, and all persons and entities acting in concert or participation with them, are enjoined until the day after the expiration of the '645 Patent and its associated pediatric exclusivity from making, using, selling, or offering for sale in the United States, or importing into the United States, the darunavir tablets described in the Lupin ANDA, ANDA 202073, or any darunavir product that includes darunavir ethanolate in a darunavir/ethanol ratio of approximately 1:1 or any colorable variation thereof.

(ECF No. 944 at 1 ¶ 2, 2 ¶¶ 6-7).

The underlying trial Opinion states in relevant part on pages 88, 97 and 99:

The Court . . . grants a permanent injunction enjoining Lupin from commercially manufacturing, selling or offering for sale, using, or importing the generic darunavir tablets described in Lupin's ANDA in the United States, or any darunavir product that includes a bis-THF component made by any colorable variation of the process used to make Lupin's ANDA products, until after the expiration date of the '015 Patent.

The Court . . . grants a permanent injunction enjoining Lupin from commercially manufacturing, selling or offering for sale, using, or importing the generic darunavir tablets described in the Lupin ANDA, or any colorable variations of the same, until after the expiration date of the '645 Patent and its associated exclusivity.

[T]his Court . . . will enter an order under 35 U.S.C. § 271(e)(4)(A) directing the FDA not to approve Lupin's ANDA until after the expiration of the '645 Patent and any associated period of pediatric exclusivity.

(ECF No. 943 at 88, 97, 99).

Lupin appealed this Court's final judgment to the Federal Circuit, where the action is fully briefed and currently pending.

On May 26, 2016, the parties settled this action, conditioned upon modification of the Final Judgment Order as described herein. The Agreement will permit the manufacture and sale of Lupin's ANDA Products on a specified date prior to expiration of the Patents-in-suit. To give practical effect to the terms of the Agreement, however, Lupin must be free to market Lupin's ANDA Products consistent with the terms of the Agreement. Effectuation of the parties' Agreement, therefore, requires that the Final Judgment Order be modified to amend the injunction entered against Lupin, to allow Lupin to manufacture, use, sale, offer for sale and import Lupin's ANDA Products pursuant to the terms of the Agreement during the terms of the Patents-in-suit. A copy of the parties' proposed Order entering the modified judgment is attached hereto as Exhibit A.



## ARGUMENT

### **I. Partial Relief from the Opinion and Final Judgment Order May Be Granted Under Federal Rule of Civil Procedure 60(b) to Give Effect to the Parties' Settlement.**

Federal Rule of Civil Procedure 60(b) provides that “[o]n motion and just terms, the court may relieve a party . . . from a final judgment, order, or proceeding.” Several reasons justify relief under Rule 60(b), two of which apply here. *See* FED. R. CIV. P. 60(b)(5), (6).

Under Rule 60(b)(5), a district court may modify a final judgment where “applying [the final judgment] prospectively is no longer equitable.” FED. R. CIV. P. 60(b)(5). Parties seeking modification of a final judgment pursuant to this provision must demonstrate that a significant change in circumstances warrants revision of the judgment. *Rufo v. Inmates of Suffolk Cty. Jail*, 502 U.S. 367, 383 (1992). Once the movant has met that burden, the Court should then “consider whether the proposed modification is suitably tailored to the changed circumstance.” *Id.*; *accord Agostini v. Felton*, 521 U.S. 203, 215 (1997) (applying *Rufo* standards to modifications of injunctions in final judgments). Here, continued application of the injunction against Lupin in the Final Judgment Order would no longer be equitable: it would defeat the key feature of the parties’ settlement—i.e., the grant of a license to Lupin. Such a result would be in direct contravention of the parties’ intent as well as the strong policy favoring settlement.<sup>1</sup> For this reason, the Agreement provides that it will not be effective, and the appeal proceedings will proceed, if the Final Judgment Order is not modified in the manner requested herein.

The relief requested herein is “suitably tailored to the changed circumstance,” *Rufo*, 502 U.S. at 383; that is, the settlement as reflected in the Agreement. The parties seek to modify the

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<sup>1</sup>*See, e.g., Pennwalt Corp. v. Plough, Inc.*, 676 F.2d 77, 80 (3d Cir. 1982) (“There is a strong judicial policy in favor of parties voluntarily settling lawsuits.”); *N.J. Dep’t of Env’tl. Prot. v. Gloucester Env’tl. Mgmt. Servs., Inc.*, 668 F. Supp. 404, 407 (D.N.J. 1987).

Final Judgment Order in a limited manner to amend the injunctive relief provisions that would prevent Lupin from realizing the benefit of the settlement. The underlying findings of fact and conclusions of law set forth in the Opinion other than the text at pages 88, 97 and 99 quoted above would remain intact. For this reason, the requested modification should be approved by the Court under Rule 60(b)(5).

Further, under Federal Rule of Civil Procedure 60(b)(6), a district court may amend or modify a final judgment “for any . . . reason justifying relief.” *Kirby Forest Indus., Inc. v. United States*, 467 U.S. 1, 18 (1984). The Agreement, which is expressly conditioned upon this Court’s grant of the parties’ joint Rule 60 motion, unquestionably constitutes a clear “reason that justifies relief” from the injunction provisions of the Final Judgment Order. *Tommy Hilfiger Licensing, Inc. v. Costco Cos., Inc.*, No. 99CIV3894-LMM-JCF, 2002 WL 31654958, at \*3 (S.D.N.Y. Nov. 25, 2002) (issuing “indicative ruling” whereby the court, upon remand, would vacate judgment in light of settlement conditioned upon vacatur of judgment); Order at 2, *Karl Storz Imaging, Inc. v. Pointe Conception Med., Inc.*, Case No. CV09-08070 GAF (C.D. Cal. Apr. 2, 2012), ECF No. 331 (issuing “indicative ruling” whereby the court, upon remand, would allow dismissal of all pending claims and counterclaims based on the parties’ having reached a settlement agreement)<sup>2</sup>; *United States v. Rodriguez*, No. 98-362-12, 2010 WL 5093908, at \*3 (E.D. Pa. Dec. 13, 2010) (issuing “indicative ruling” whereby the court, upon remand, would grant defendant’s Rule 60(b) motion).

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<sup>2</sup>See also *Karl Storz Imaging, Inc. v. Pointe Conception Med., Inc.*, No. 2012-1001, 2012 WL 2884704, at \*1 (Fed. Cir. July 16, 2012) (granting motion to remand in light of District Court’s indicative ruling that, upon remand, it would vacate the underlying judgment based on the parties’ settlement agreement).

**II. Federal Rule of Civil Procedure 62.1 Authorizes an “Indicative Ruling” by this Court, to Be Given Effect upon Remand from the Appellate Court.**

The need for modification of the Final Judgment Order has arisen while this Court is divested of jurisdiction in light of the pending appeal. Under these circumstances, Federal Rule of Civil Procedure 62.1, together with Federal Rule of Appellate Procedure 12.1, describe the procedure this Court should follow in entertaining a Rule 60(b) motion. *See Acoustic Techs., Inc. v. Itron, Inc.*, No. 2011-1315, 2011 WL 3893811, at \*1 (Fed. Cir. Sept. 6, 2011); FED. R. APP. P. 12.1, 2009 advisory committee’s note (stating that Rule 12.1 “corresponds to Federal Rule of Civil Procedure 62.1”). Under Federal Rule of Civil Procedure 62.1(a), “[i]f a timely motion is made for relief that the court lacks authority to grant because of an appeal that has been docketed and is pending, the court may . . . state [] that it would grant the motion if the court of appeals remands for that purpose . . . .” FED. R. CIV. P. 62.1(a). If the court makes such a statement, then “[t]he movant must promptly notify the circuit clerk under Federal Rule of Appellate Procedure 12.1 if the district court states that it would grant the motion . . . .” FED. R. CIV. P. 62.1(b). On remand, “[t]he district court may decide the motion if the court of appeals remands for that purpose.” FED. R. CIV. P. 62.1(c).

The parties jointly request that the Court, consistent with this procedure, issue an Indicative Ruling to amend the Final Judgment Order and amend the injunction as applicable to Lupin. If and when the Court issues the requested ruling, the parties will jointly request that the Federal Circuit remand the case to this Court to allow for modification of the Final Judgment Order to amend the injunction provisions therein relevant to Lupin. In the event that the Court refrains from entering an Indicative Ruling of the nature described herein, the parties’ Agreement will not take effect, and the parties will proceed with the currently-pending appeal.

**CONCLUSION**

For the reasons set forth above, the parties respectfully request that the Court issue an Indicative Ruling pursuant to Federal Rule of Civil Procedure 62.1 stating that the Court would enter an order modifying the Final Judgment Order and amending the injunctive relief provisions relevant to Lupin to allow permitted activities under the Agreement, were the Federal Circuit to remand the case for this purpose.

Respectfully submitted,

**MCCARTER & ENGLISH LLP**

*Attorneys for Plaintiffs/Counterclaim-  
Defendants Janssen Products, L.P.  
and Janssen Sciences Ireland UC*

By: /s/ John E. Flaherty

John E. Flaherty (jflaherty@mccarter.com)  
100 Mulberry Street  
Four Gateway Center  
Newark, New Jersey 07102  
Telephone: (973) 639-7903

Of Counsel

Gregory L. Diskant (gldiskant@pbwt.com)  
Eugene M. Gelernter  
(emgelernter@pbwt.com)  
Irena Royzman (iroyzman@pbwt.com)  
**PATTERSON BELKNAP WEBB & TYLER LLP**  
1133 Avenue of the Americas  
New York, New York 10036  
Telephone: (212) 336-2000

Dated: June 7, 2016

**CARELLA, BYRNE, CECCHI, OLSTEIN,  
BRODY & AGNELLO, P.C.**

*Attorneys for Defendants/Counterclaim-  
Plaintiffs Lupin Limited and Lupin  
Pharmaceuticals, Inc.*

By: /s/ Melissa E. Flax

James E. Cecchi  
(JCecchi@carellabyrne.com)  
Melissa E. Flax  
(mflax@carellabyrne.com)  
5 Becker Farm Road  
Roseland, New Jersey 07068-1739  
Telephone: (973) 994-1700

Of Counsel

William A. Rakoczy  
(wrakoczy@rmmslegal.com)  
Deanne M. Mazzochi  
(dmazzochi@rmmslegal.com)  
Amy D. Brody (abrody@rmmslegal.com)  
Tara M. Raghavan  
(traghavan@rmmslegal.com)  
**RAKOCZY MOLINO MAZZOCHI SIWIK LLP**  
6 West Hubbard Street, Suite 500  
Chicago, Illinois 60654  
Telephone: (312) 222-6301